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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,327	12/08/2003	B. Stuart Trembly	414176	2384
30955	7590	03/28/2006		
LATHROP & GAGE LC 4845 PEARL EAST CIRCLE SUITE 300 BOULDER, CO 80301			EXAMINER FARAH, AHMED M	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/730,327	Applicant(s) TREMBLY, B. STUART	
	Examiner Ahmed M. Farah	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/08/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 17 recites "the applicator of claim 17" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by the Applicant's Admitted Prior Art (AAPA) shown in Figure 1 of the instant application.

As described in paragraphs 6 through 8 of the applicant's written description, Figure 1 depicts a side of mid-sectional view of conventional microwave applicator for use in thermokeratoplasty operations, the applicator comprising:

an electrically conducting element comprising at least a pair of elongated conductors (electrodes 104, 106) separated by a selected distance and extending from a proximal end to a distal end;

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an insulator (dielectric material 108) disposed between said two conductors to provide electrical insulation therebetween;

a thermally conductive dielectric element (Mylar film 108) thermally coupled to said conductors at said distal end, said dielectric element being adapted for positioning on a portion of a patient's cornea 102 at interface 122; and

a cooling device 122 thermally coupled to said dielectric element (Mylar film 108) for cooling thereof, wherein application of an electrical signal across said two conductors at said proximal end causes generation of electrical energy at said distal end penetrating said dielectric element (Mylar film 108).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-20, and 25-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shadduck US Patent No. 6,053,909.

Shadduck discloses a radio-frequency applicator for use in keratoplasty operations (see Figs. 12A-12C and col. 14, line 36+), the applicator comprising:

a pair of electrodes separated by a selected distance and extending from a proximal end to a distal end, said electrodes configured to have a direct contact with

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corneal tissue; a dielectric insulator (optical fiber 55) disposed between the electrodes; an RF generator for providing the treatment energy; and a feedback system for monitoring and controlling the treatment energy (see Figs. 3-5, 7-8B, and 12A-12C).

Shadduck does not teach that the bottom surface of the conducting element element/electrode is partially coated with thermally conductive and electrically insulating material as presently claimed. However, it is known in the medical art to dispose electrically insulating coating on the forward end of an electrode to prevent direct contact between the body tissue and the conductor end so as to limit collateral tissue damage. Furthermore, although the optical fiber 55 of Shadduck is not intended for insulation between the electrodes, it inherently prevents the possibility of unwanted electrical interactions between the electrodes.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Doss US Patent No. 4,381,007.

Shadduck, described above, does not teach a vacuum source configured to apply suction to at least a portion of the corneal tissue as claimed. However, the use of negative pressure to position a medical device on a tissue surface is known in the art. Doss teaches an alternative keratoplasty apparatus comprising at least a pair of electrodes and a vacuum system for positioning the apparatus on corneal surface. Therefore, at the time of the applicant's invention, it would have been obvious to one skilled in the art to modify Shadduck in view of Doss and use a vacuum source in order to position the treatment device on corneal surface of the eye. Properly positioning and securing the device on the treatment area would prevent undesired movement of the

apparatus in relation to the eye during treatment. This would further prevent exposure of treatment energy to undesired tissue region.

Claims 2 and 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the AAPA in view of Doss ('007) and Ryan et al. US Patent No. 6,224,593.

The AAPA fails to teach concentric electrode design, dimensions of the electrodes, or a thermally dielectric material coated on the electrodes as presently claimed. However, the use of concentric electrodes or a thin dielectric material coated on the distal end of a conductor is known in the medical art. Doss, described above, discloses keratoplasty apparatus comprising a concentric bipolar electrode (see Figs. 7 and 8). Ryan et al. disclose a medical device comprising concentric electrode system in which thin dielectric material is coated at least on the distal end of one of the conductors.

Therefore, at the time of the applicant's invention, it would have been obvious to one skilled in the art to use concentric electrodes as an equivalent alternative energy conductor to deliver the treatment energy. It would have been further obvious to one skilled in the art to use a thin dielectric coating on the distal end of an electrode to prevent direct contact between body tissue and the conductor end to limit collateral damage to the tissue.

As to claims 7 and 8, the applicant has not disclosed that the dimensions/ diameters of the conductor tubes provides an advantage, is used for a particular purpose, or solves a stated problem. Hence, at the time the invention was made, it would have been obvious to one skilled in the art to use a concentric electrode system

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comprising an outer conducting tube and inner conducting tube, the outer conducting tube having a diameter larger than the diameter of the inner tube, wherein the diameter of the outer tube is suitable eye treatment. Furthermore, one skilled in the art would have expected Applicants' invention to perform equally well with various diameters of the tubes because no advantage is disclosed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 15, 2006.

AHMED FARAH
PRIMARY EXAMINER

